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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,419	07/22/2003	Michael J. Rice	54563US011	7244

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EXAMINER

HUANG, EVELYN MEI

ART UNIT PAPER NUMBER

1625

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/624,419

Applicant(s)

RICE ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-8 and 13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,6-8 and 13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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DETAILED ACTION

1. Claims 1, 6-8, 13 are pending. Claims 2-5, 9-12, 14-16 have been canceled according to the preliminary amendment filed on 7-22-2003.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6-8, 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1,

- Definition of R1, the first spacer group, should it be -NH- instead of the recited -N- ?
- What are the heteroatoms, the number and positions of the heteroatoms in the 5-7-membered ring formed by R3 and R4?

This rejection is applicable to claims dependent on claim 1.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-8, 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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a. *Nature of the invention.*

The instant invention is drawn to dye labeled imidazoquinoline compound with cytokine biosynthesis inducing activity.

b. *State of the prior art and the level of the skill in the art.*

Imidazo[4,5-c]quinolin-4-amine derivatives are also known to induce interferon biosynthesis (Gerster, 5266575, PTO-1449, columns 9-10). Certain imidazo[4,5-c] quinoline compounds have been shown to induce TNF and IL-1 production (Testerman, PTO-1449, abstract).

The level of the skill in the cytokine production inducer art is high.

c. *Predictability/unpredictability of the art.*

The high degree of unpredictability is well recognized in the cytokine biosynthesis art. A slight change in the structure of the compound would drastically change its biological activity as evidenced in the different values of structurally similar compounds in the interferon bioassay and the different anti-viral activities by the same compounds in the type II Herpes simplex-infected guinea pigs (Gerster, columns 9-10). Structurally similar imidazo[4,5-c] quinoline compounds have different profiles in the induction of the different cytokines (page 367, 368, Table 1 and Table 2). One of ordinary skill in the art would have no basis to extrapolate the tested results to compounds with dissimilar structures.

d. *Amount of guidance/working examples.*

How to make

The preparation of the 3 example compounds is limited to imidazoquinoline compounds (i.e. R3 and R4 together form an aromatic 6-membered ring) linked to a dipyrrometheneboron difluoride dye or a fluorescein dye.

Starting materials and the process of making the instant compounds (wherein R3 and R4 together form a 5-7-membered saturated ring optionally containing one or more heteroatoms, wherein the number, the positions of these heteroatoms have not been fully described) are not described in the specification but are required. Absent sources, the public is offered mere language, rather than enablement. Ex parte Moersch 104 USPQ 122. In re Howarth 210 USPQ 689.

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How to use

Procedures for measuring cytokine induction in human cells by the inventive compound are described in Test method 1 and 2. The results are shown for the 3 example compounds.

e. *Breadth of the claims.*

Applicant's assertion that all the structurally diverse compounds (imidazopyridine fused to a 5-7-membered saturated ring formed by R3 and R4, optionally containing one or more heteroatoms) would be effective inducers of cytokines, does not commensurate with the scope of the objective enablement, especially in view of the high degree of unpredictability in the art and the absence of working examples directed to the instantly claimed compound (paragraphs c, d above).

f. *Quantitation of undue experimentation.*

Since insufficient guidance and teaching have been provided by the specification (paragraphs c-e above), one of ordinary skill in the art, even with high level of skill, is unable to make and use the instant compound as claimed without undue experimentation.

Conclusion

4. No claims are allowed.


Substituted dipyrromethenboron difluoride derivatives are described by Kang (5187288, 5274113, PTO-1449) and Haugland (5248782, PTO-1449) Lindstrom (5494916, PTO-1449) discloses the imidazo-pyridin-4-amine while Gerster (4949624, 4689338, PTO-1449) discloses the imidazoquinolin-4-amine. However, the instant dyed-labeled imidazo-pyridine fused to a 5-7-membered ring optionally containing one or more heteroatoms is not taught or suggested by the prior art of record.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Evelyn Huang
Primary Examiner
Art Unit 1625
